

# **EXHIBIT 17**

CONFIDENTIAL

Page 1

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- - - - -  
In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

Civil Action No. 16-cv-4187

(JNE/FLN)

This Document Relates To:

Gareis v 3M Co., et al

- - - - -

DEPOSITION OF BRADLEY P. PRESNAL, M.D.

VOLUME I, PAGES 1 - 183

DECEMBER 4, 2017

(The following is the deposition of BRADLEY P. PRESNAL, M.D., taken pursuant to Notice of Taking Deposition, via videotape, at the offices of Palmetto Health-USC Orthopedic Center Convenient Care Building, 101 Business Park Boulevard, in the City of Columbia, State of South Carolina, commencing at approximately 6:05 o'clock p.m., December 4, 2017.)

## CONFIDENTIAL

<p style="text-align: center;">Page 14</p> <p>1 Q. Okay. How are instruments sterilized?</p> <p>2 <b>A. I don't know if I can get into the technical</b>  <b>3 part of it, but it basically is a high pressure, high</b>  <b>4 temperature steam sterilizer.</b></p> <p>5 Q. Okay. Do you consider the hospital is    6 competent to sterilize instruments?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Do you have any reason to believe that the    9 instruments in Mr. Gareis's case were contaminated and    10 caused the infection?</p> <p>11 <b>A. Not -- Not that I remember. You know, the</b>  <b>12 -- all the sterilized instruments have indicators that</b>  <b>13 show whether they've reached the right temperature and</b>  <b>14 pressure to show that they've gone through the cycle</b>  <b>15 correctly, so that's always checked.</b></p> <p>16 Q. Any reason to believe that the implant was    17 contaminated?</p> <p>18 <b>A. No.</b></p> <p>19 Q. Do you engage in skin antisepsis? I think    20 you touched on that a moment ago.</p> <p>21 <b>A. Yeah. We probably started this in 2005,</b>    22 <b>maybe earlier. We have patients do Hibiclens showers</b>    23 <b>the night before and the morning of. So they take a</b>    24 <b>shower with a special antibiotic soap the night before</b>    25 <b>surgery, the morning they come in, and then we -- for</b></p>	<p style="text-align: center;">Page 16</p> <p>1 <b>A. So we typically have signs on the outer door</b>    2 <b>saying, you know, don't come in unless you have to</b>    3 <b>come in. We limit any traffic that has to come in</b>    4 <b>must come in through the sterile -- sterile corridor.</b>    5 <b>We don't allow traffic to come in from the out --</b>    6 <b>outer design. If you look, the -- the OR's have an</b>    7 <b>outer corridor and a inner sterile corridor so the</b>    8 <b>traffic that does come into the room has to come</b>    9 <b>through the sterile corridor.</b></p> <p>10 Q. Okay. Do you recall, in Mr. Gareis's case,    11 whether there was any unusual movement in and out of    12 the operating room?</p> <p>13 <b>A. Not that I remember, no.</b></p> <p>14 Q. When staff members do have to come in during    15 the surgery, do they utilize the sterile door?</p> <p>16 MR. GORDON: Object to the form of the    17 question.</p> <p>18 <b>A. Yes. We tell them they have to come in that</b>    19 <b>way, and we -- you know, certainly there may be rare</b>    20 <b>cases where somebody doesn't know or comes in, but</b>    21 <b>it's very unusual.</b></p> <p>22 Q. Have any reason to believe that that    23 protocol was not followed in this case?</p> <p>24 <b>A. No.</b></p> <p>25 Q. Does the operating room theatre have a</p>
<p style="text-align: center;">Page 15</p> <p>1 the surgery we use a skin prep which is typically    2 either Dur -- a DuraPrep or ChloraPrep. Both are    3 alcohol based with either chlorhexidine or iodine    4 component.</p> <p>5 Q. Is there anything done as far as prep of the    6 skin goes before making your incision?</p> <p>7 <b>A. So that's the -- that's the DuraPrep or</b>    8 <b>ChloraPrep's put on the skin.</b></p> <p>9 Q. Uh-huh.</p> <p>10 <b>A. And then we use Ioban, which is a thin kind</b>    11 <b>of plastic-type membrane that sticks to the skin that</b>    12 <b>seals the drapes or helps keep the drapes in place.</b></p> <p>13 Q. And do you cut through that when making your    14 incision?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. And what is that designed to do?</p> <p>17 <b>A. Well it -- it -- it's designed to cut on --</b>    18 <b>or to cut down on the amount of bacteria migration to</b>    19 <b>the skin, to -- to the edge of the incision.</b></p> <p>20 Q. Okay. When you make your incision do you    21 use retractors to pull that away?</p> <p>22 <b>A. Yes.</b></p> <p>23 Q. Let's talk about movement in and out of the    24 operating room. Do you do anything to attempt to    25 limit movement during these types of surgeries?</p>	<p style="text-align: center;">Page 17</p> <p>1 ventilation system?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. And was this the type of system that    4 introduces clean air into the OR?</p> <p>5 <b>A. As far as I know when we -- when we looked</b>    6 <b>at this, especially when I was involved with the</b>    7 <b>renovations, we looked a lot at the airflow because</b>    8 <b>it's important with joint replacement, so -- because</b>    9 <b>we looked at possibly installing laminar flow, which</b>    10 <b>is a little bit controversial as to whether it reduces</b>    11 <b>infection. But basically what laminar flow is a</b>    12 <b>unidirectional high exchange, so we found that what</b>    13 <b>they had was still high exchange unidirectional flow</b>    14 <b>which is basically laminar flow, it's just not the</b>    15 <b>name for it.</b></p> <p>16 Q. Okay. And why is it important to have    17 unidirectional flow?</p> <p>18 <b>A. Because there have been studies that show</b>    19 <b>that turbulent flow increases your risk of infection.</b>    20 <b>So you want the airflow to be top down so that it's</b>    21 <b>not pulling up things from the ground, so it's always</b>    22 <b>pushing things down towards the floor.</b></p> <p>23 Q. Is reducing particulates in the air    24 something you care about as the orthopedic surgeon?</p> <p>25 <b>A. Sure.</b></p>

## CONFIDENTIAL

<p style="text-align: right;">Page 18</p> <p>1 Q. Let's talk a little bit about the -- the 2 implant itself. What type of implant did you put in 3 Mr. Gareis?</p> <p>4 <b>A. It was a -- a system from DePuy. The stem</b> 5 <b>was a CORAIL stem. The typical implant that I use</b> 6 <b>with that, the acetabular component is a PINNACLE. It</b> 7 <b>had a polyethylene liner, Ultrex liner, and then he</b> 8 <b>had a 40 millimeter metal head.</b></p> <p>9 Q. Okay. So it was not a metal-on-metal 10 system?</p> <p>11 <b>A. No.</b></p> <p>12 Q. Is the implant sterile before you place it?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. Okay. So when you place an implant for 15 doing a total hip such as Mr. Gareis, how is it that 16 you get the implant from the packaging into the 17 patient?</p> <p>18 <b>A. So typically there is a two-stage</b> 19 <b>packaging -- packaging for all sterile implants,</b> 20 <b>there's an outer portion that the scrub nurse will</b> 21 <b>open and hand it to the scrub tech, so they handle it</b> 22 <b>from off side the -- out of the sterile field onto the</b> 23 <b>sterile field. Then there's another package that the</b> 24 <b>scrub nurse or scrub tech will open to expose the</b> 25 <b>implant so that you can implant it.</b></p>	<p style="text-align: right;">Page 20</p> <p>1 <b>that point we had switched from staples to doing --</b> 2 <b>Well let me make sure I'm telling you right because</b> 3 <b>I'm not sure of the time we switched that. (Witness</b> 4 <b>reviewing documents.) No, we did use staples in his</b> 5 <b>case. We've gotten away from staples as well.</b></p> <p>6 <b>Sterile dressings. We tell them not to</b> 7 <b>shower for the first -- when we're using staples, for</b> 8 <b>the first three days. So those are our sort of</b> 9 <b>standard measures.</b></p> <p>10 Q. As you recall, was Mr. Gareis typically a 11 compliant patient?</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Do you have any reason whatsoever to believe 14 that you or your staff failed to follow all the 15 protocols that you just described?</p> <p>16 <b>A. No. I think, you know, at that point we're</b> 17 <b>pretty regimented with how we approach hip and knee</b> 18 <b>replacement so we were doing all the things that we</b> 19 <b>knew to do back then.</b></p> <p>20 Q. Okay. We're here because of a 21 patient-warming device, want to talk to you a little 22 bit about patient warming.</p> <p>23 You understand it's become common practice 24 to warm patients during surgery; --</p> <p>25 <b>A. Yes.</b></p>
<p style="text-align: right;">Page 19</p> <p>1 Q. And then how do you physically get it out of 2 the package into the -- into the patient?</p> <p>3 <b>A. So we try and use as little touch -- no</b> 4 <b>touch when we can. Some things it's almost impossible</b> 5 <b>to do that. So for the acetabular component there's a</b> 6 <b>handle that is attached, usually screws into the</b> 7 <b>socket part, and that is your impactor, you use the</b> 8 <b>handle, again trying not to touch the component as</b> 9 <b>much as we can, place that in and -- and basically</b> 10 <b>hammer it into place. For the stem, same thing;</b> 11 <b>there's a handle that either screws in or locks onto</b> 12 <b>the stem part and it is hammered into the femur, or</b> 13 <b>impacted.</b></p> <p>14 Q. Okay. And did you do that in Mr. Gareis's 15 case?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. Are there any other infection control 18 measures that we haven't talked about that you or the 19 OR staff follows?</p> <p>20 <b>A. Well we do -- the antibiotics are, you know,</b> 21 <b>twenty -- are before surgery. The timing of that's</b> 22 <b>critical so we try and do that within 30 minutes to an</b> 23 <b>hour of cut time. We keep people on prophylactic</b> 24 <b>antibiotics in the hospital for 24 hours IV</b> 25 <b>antibiotics. We use, you know, sterile dressings. At</b></p>	<p style="text-align: right;">Page 21</p> <p>1 Q. -- right? 2 Do you know what it's intended to do?</p> <p>3 <b>A. I think the -- the basis is that they have</b> 4 <b>shown -- there's some studies that show that keeping a</b> 5 <b>patient warm decreases infection. From -- From my</b> 6 <b>reading that is mainly in the general surgery realm.</b> 7 <b>As far as I know, there's not a lot of published data</b> 8 <b>in the orthopedic realm on that.</b></p> <p>9 Q. Well you bring up a good point. 10 Do you know whether there's any solid 11 evidence that supports the benefit of using patient 12 warming during a total knee or total hip surgery?</p> <p>13 <b>A. Not -- Not that --</b></p> <p>14 MR. GORDON: Object to the form of the 15 question, also lack of foundation.</p> <p>16 <b>A. Not that I've read, no.</b></p> <p>17 Q. Okay. Do you subscribe to any orthopedic 18 journals?</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. Or any general medical journals?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. Do you feel like you keep abreast of the 23 latest developments regarding orthopedic surgery?</p> <p>24 <b>A. So I try to, and the other thing I typically</b> 25 <b>do is I try and make it to the national meeting as</b></p>

## CONFIDENTIAL

<p style="text-align: right;">Page 146</p> <p>1       <b>A. I wouldn't --</b></p> <p>2            MR. HODGES: Objection, form.</p> <p>3       <b>A. -- say "infinite," but there are a lot of --</b></p> <p>4       <b>there are several different ways, again depending on</b></p> <p>5       <b>which -- if you divide it into time frames. That's</b></p> <p>6       <b>how I think of it. Intraoperative, perioperative, and</b></p> <p>7       <b>again perioperative can be different depending on who</b></p> <p>8       <b>is making that definition of the timeframe, or late</b></p> <p>9       <b>infection, chronic infection which could be a</b></p> <p>10       <b>hematogenous spread, some type of infection somewhere</b></p> <p>11       <b>else in the body goes there. And that could be any</b></p> <p>12       <b>type of infection, although the typical ones are going</b></p> <p>13       <b>to be some type of septic episode where they've had an</b></p> <p>14       <b>infection somewhere else but they get bacteria in the</b></p> <p>15       <b>blood and it goes to the hip.</b></p> <p>16       <b>So I would consider all those -- they're</b></p> <p>17       <b>different sources, but that's all one type of</b></p> <p>18       <b>infection. Again there's lots of different sources it</b></p> <p>19       <b>could come from, but it's sort of one way to get</b></p> <p>20       <b>there, hematogenous spread through the blood.</b></p> <p>21       Q. Now earlier, when Mr. Hodges was asking you</p> <p>22       questions, you said something about the hospital was</p> <p>23       evaluating airflow, or you were -- maybe it was your</p> <p>24       group.</p> <p>25       <b>A. Right. Right.</b></p>	<p style="text-align: right;">Page 148</p> <p>1       <b>evaluation, so.</b></p> <p>2            <b>But what you wanted was a certain level of</b></p> <p>3       <b>full-room exchanges per minute or per hour, I can't</b></p> <p>4       <b>remember what the parameter was. So unidirectional</b></p> <p>5       <b>flow, a certain number of changes per minute or per</b></p> <p>6       <b>hour. And that's what we wanted was to make sure that</b></p> <p>7       <b>we were -- at least the airflow in the room was of the</b></p> <p>8       <b>quality of a laminar flow. So we looked at the rooms</b></p> <p>9       <b>that we currently used and the new rooms to make sure</b></p> <p>10       <b>we were going to get that type of airflow in all of</b></p> <p>11       <b>the rooms.</b></p> <p>12       Q. And the -- the downward flow from the</p> <p>13       ceiling, where does it go out?</p> <p>14       <b>A. I can't know that I can answer that. So it</b></p> <p>15       <b>goes straight down and you hope it goes away from the</b></p> <p>16       <b>operative field. That's what you hope.</b></p> <p>17       Q. Okay. You're not aware of the location of</p> <p>18       any vents on the --</p> <p>19       <b>A. I -- I assume there is, but I don't really</b></p> <p>20       <b>know.</b></p> <p>21       Q. You described a door leading to a -- the --</p> <p>22       I think you described it as a sterile corridor.</p> <p>23       <b>A. Sterile core, yes.</b></p> <p>24       Q. And when you used the words "the sterile</p> <p>25       core," the corridor itself is not sterilized; right?</p>
<p style="text-align: right;">Page 147</p> <p>1       Q. What prompted that?</p> <p>2       <b>A. So when we were adding the new ORs, one of</b></p> <p>3       <b>our discussions was, since we knew we were going to be</b></p> <p>4       <b>doing a high percentage of joint replacements there,</b></p> <p>5       <b>should we add laminar flow. So again it's a little</b></p> <p>6       <b>bit controversial as to whether it actually decreases</b></p> <p>7       <b>the risk; some people believe it does, some people</b></p> <p>8       <b>don't. But what we found out through our research was</b></p> <p>9       <b>laminar flow is almost a trademark. It is a</b></p> <p>10       <b>unidirectional flow with a high exchange rate. So you</b></p> <p>11       <b>can actually have the same thing as laminar flow, but</b></p> <p>12       <b>not have to buy laminar flow, if that makes sense.</b></p> <p>13       <b>It's kind of like buying Coke, or going and buying</b></p> <p>14       <b>generic cola. You can get the same thing, but you're</b></p> <p>15       <b>just not paying for the name.</b></p> <p>16       So laminar flow, we found out, was really</p> <p>17       more of a brand. So what we wanted was a</p> <p>18       unidirectional flow so the air flows from the ceiling</p> <p>19       to the floor in one direction, doesn't go in multiple</p> <p>20       directions. So you have a air vent above the</p> <p>21       operative flow --</p> <p>22       Q. I think they call it a plenum, does that</p> <p>23       sound?</p> <p>24       <b>A. It may be. I don't know. I can't get that</b></p> <p>25       <b>technical. But this is what I learned in our</b></p>	<p style="text-align: right;">Page 149</p> <p>1       MR. HODGES: Objection, form.</p> <p>2       <b>A. No. It's just more -- more barriers from</b></p> <p>3       <b>the outside. So more doors to the -- between the</b></p> <p>4       <b>operating room and the outside. So it's an extra door</b></p> <p>5       <b>from the outside is what we're trying to use. And you</b></p> <p>6       <b>can't go into that sterile core with your mask down.</b></p> <p>7       <b>When I say you can't, you're instructed not to. If</b></p> <p>8       <b>you're in the sterile core your mask has to be up. So</b></p> <p>9       <b>in the outside areas around the OR you can walk around</b></p> <p>10       <b>without a mask, but in this part of the OR, the</b></p> <p>11       <b>sterile core, you can only go in with head cover, mask</b></p> <p>12       <b>and everything. So it's kind of like an operating</b></p> <p>13       <b>room, but you don't do any surgery in there.</b></p> <p>14       Q. And to get from the OR to the doctor's</p> <p>15       lounge you go through the sterile core?</p> <p>16       <b>A. Sterile core, yes.</b></p> <p>17       Q. Okay. So the procedure would be to wear</p> <p>18       head -- head covering and mask through that.</p> <p>19       <b>A. Yes.</b></p> <p>20       Q. But once you get to the doctor's lounge you</p> <p>21       can take that off?</p> <p>22       <b>A. You can take the mask off.</b></p> <p>23       Q. Take the mask off but not the head covering?</p> <p>24       <b>A. Typically once you're back there you're</b></p> <p>25       <b>going to keep the head cover on. You put it on first</b></p>